

September 24, 1996 to and including December 24, 1996. If any further fees are required they should be taken from Deposit Account Number 08-3255 and advise Applicants' Agent. Applicants respectfully request that the following submissions be entered.

In respect of the required Information Disclosure Statements (IDS), Applicants enclose copies of the IDS filed with respect to the parent Patent Application 07/675,908 together with requisite fee of \$220.00 US to cover the cost of filing such IDS. In accordance with 1.98(d), the documents referred to therein are not included and can be examined in the prosecution file history of Parent Patent Application 07/675,908.

In respect of the objection to the disclosure due to informalities, Applicants enclose a single sided copy of the disclosure which includes the specification and claims on separate pages. No new matter has been added.

IN THE CLAIMS

Please amend the claims as follows:

11. (Amended) A method of treating a condition or disease in a mammal comprising administering to the mammal a therapeutically effective amount of an agent selected from the group consisting of a medicine and a therapeutic agent and combinations thereof [a medicinal and/or therapeutic agent] to treat the disease or condition and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and/or salts and/or homologues, analogues, derivatives, complexes, esters, fragments, and sub-units of hyaluronic acid thereof] sufficient to facilitate the penetration of the agent through the tissue [(including scar tissue)] at a [the] site to be treated through the cell membranes into the individual cells to be treated wherein the

C1 cont'd
molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

C2
122. (Amended) A dosage amount of a pharmaceutical composition for treating [For use to treat] infection, said dosage amount comprising [the administration of] a therapeutically effective amount of an agent selected from the group consisting of antibiotics, antibacterials, antimicrobials and combinations thereof [therof] with or without ascorbic acid and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

3 123. (Amended) The dosage amount [For the use] of Claim 122 wherein the form of hyaluronic acid [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid is hyaluronic acid and/or salts thereof] is sodium hyaluronate.

C3
151. (Amended) A dosage amount of a pharmaceutical composition for treating [For use to treat] infections surrounding implants in a patient, said dosage amount comprising [the administration of] a therapeutically effective amount of an antibiotic for the infected tissue surrounding the implant and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and

B

C3
contd

its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

C4

187. (Amended) A method of treating [For use to treat] infection, the method comprising the administration [combination] of a therapeutically effective amount of an agent selected from antibiotics, antibacterials, antimicrobials and combinations thereof [therof] with or without ascorbic acid and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

C5

216. (Amended) A method of treating [For use to treat] infections surrounding implants in a patient, the method comprising the administration [the combination] of a therapeutically effective amount of an antibiotic for the infected tissue surrounding the implant ⁶and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues,

Sub
C5
contd

derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

C6 7 218. (Amended) The method [combination] of Claim ~~216~~⁶ [or 217] wherein the form of hyaluronic acid [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid is hyaluronic acid and/or salts thereof] is sodium hyaluronate.

C7 261. (Amended) A dosage amount of a pharmaceutical composition for [For] the prevention of topical infection, said dosage amount comprising [the administration of] an effective amount of an anti-metabolite and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site ^{substituted} to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

9 262. (Amended) The dosage amount [For the use] of Claim ~~261~~⁸ wherein the form of hyaluronic acid [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid is hyaluronic acid and/or salts thereof] is sodium hyaluronate.

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263. (Amended) A method of preventing a [For the prevention of] topical infection, the method comprising the administration [combination] of an effective amount of an anti-metabolite and a sufficient amount of a form of hyaluronic acid selected from hyaluronic acid and its non-toxic salts and combinations thereof [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid] to facilitate the agent at a [the] site to be treated by the agents passing through the tissue [(including scar tissue)] through the cell membranes into the individual cells to be treated wherein the molecular weight of the form of hyaluronic acid is in the range of 150,000 to 750,000 daltons, and said amount of the form of hyaluronic acid is sufficient to provide a dosage greater than 10mg/70kg person.

11/264. (Amended) The method [combination] of Claim ~~263~~¹⁰ wherein the form of hyaluronic acid [and salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments and sub-units of hyaluronic acid is hyaluronic acid and/or salts thereof] is sodium hyaluronate.

REMARKS

Claims 11, 122, 123, 151, 187, 216, 218 and 261-264 remain in the application. These claims prior to amendment stand rejected on various grounds under 35 USC §112, first and second paragraphs, 102(b) and 103, all of which Applicants respectfully traverse and believe are all overcome by the instant amendment, along with the enclosed Declarations.

In the interest of advancing the prosecution of the application, Applicants have amended the forms of hyaluronic acid in the claims to hyaluronic acid and its non-toxic salts. The term "salts" does not encompass a large number of components and, in fact, would be readily understood by a person skilled in the